



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

KURT E. PETERSEN ET AL.

Application No.: 09/970,434

Filed: Oct. 2, 2001

For: DEVICE FOR ANALYZING A  
FLUID SAMPLE

Examiner: YANG, NELSON C.

Art Unit: 1641

Confirmation No.: 5347

APPELLANT'S BRIEF UNDER 37 CFR  
§ 1.192

**MAIL STOP APPEAL BRIEF - PATENTS**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicants, in the above-captioned patent application, appeal the final rejection of claims 21-35, 37 and 40. The claims on appeal have been finally rejected pursuant to MPEP § 706.07(b). Accordingly, this appeal is believed to be proper.

**I. REAL PARTY IN INTEREST:**

The real party in interest for the above-identified application is CEPHEID, a California corporation having its principal place of business at 904 Caribbean Drive, Sunnyvale, California 94089. The assignment was recorded in the U.S. Patent and Trademark Office on Sept. 14, 2000 at Reel 011181/Frame 0431.

**II. RELATED APPEALS AND INTERFERENCES:**

There are no appeals or interferences related to the present appeal.

**III. STATUS OF CLAIMS:**

Claims 21-35, 37 and 40 are pending.

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Claims 21-26, 31, 32, 35, 37 and 40 were rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522).

Claims 27-29 were rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522), as applied to claim 21 above, and further in view of Carlin [Ultrasonics, 1960, McGrar Hill].

Claim 28 was rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522), as applied to claim 21 above, and further in view of Bersted et al. (US 6,129,879).

Claim 30 was rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522), as applied to claim 21 above, and further in view of Lynnworth (US 4,335,719).

Claims 33-34 were rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522), as applied to claim 21 above, and further in view of Buechler et al. (US 6,106,779).

#### IV. STATUS OF AMENDMENTS:

Applicants filed a Response under 37 C.F.R. § 1.116 on August 8, 2005. No amendments were made. An Advisory Action mailed September 8, 2005 indicated that the Response did not place the application in condition for allowance.

In accordance with 37 C.F.R. § 1.192(c)(9), a copy of the claims involved in the appeal are contained in the Appendix attached hereto.

#### V. SUMMARY OF CLAIMED SUBJECT MATTER:

This application discloses a device (claims 21-35, 37 and 40) for extracting an analyte from a sample containing cells or viruses.

In the embodiment of independent claim 21, the device comprises a cartridge 20 having a lysing chamber 86 for lysing the cells or viruses to release the analyte therefrom. The lysing chamber contains capture material for capturing the cells or viruses in the sample as the sample flows through the lysing chamber. The capture material comprises at least one filter (94, 97) or beads (96, 99), and the lysing chamber is defined by at least one wall having an external surface. The cartridge also has at least one waste chamber 68 for receiving used

sample fluid that has flowed through the lysing chamber. The cartridge further has at least a third chamber 42 for receiving the analyte released from the cells or viruses, and the cartridge also has at least one flow controller for directing the used sample fluid, from which the cells or viruses have been separated, to flow into the waste chamber after the sample fluid flows through the lysing chamber and for directing the analyte released from the cells or viruses to flow into the third chamber. The device also comprises a transducer 92 arranged to sonicate the lysing chamber, the transducer being coupled to the external surface of the wall. See Figures 1, 3, 5, 6, and 22.

VI. GROUND OF REJECTION PRESENTED FOR REVIEW:

A. Claims 21-26, 31, 32, 35, 37 and 40 were rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522). The remaining dependent claims (27-30 and 33-34) were rejected under 35 USC 103(a) as being unpatentable over the same references, further in view of additional secondary references.

VII. ARGUMENTS:

A. Claim 21 is not properly rejected under 35 USC 103(a) as being unpatentable over Wilding (US 5,955,029) in view of Murphy (US 5,374,522), and its dependent claims are not properly rejected over the same references as well as other secondary references

Applicants respectfully submit that independent claim 21 is novel and patentable over Wilding and Murphy because, for instance, none of the references alone or in combination teach or suggest a device having a lysing chamber containing at least one filter or beads for capturing the cells or viruses in a sample as the sample flows through the lysing chamber.

In the primary reference of Wilding, a cell lysis chamber 22B has piercing protrusions 90 which tear open cells. The lysis chamber does not contain a filter or beads for capturing the cells as sample fluid flows through the chamber 22B. Instead, cells are bound to a wall surface in a separate cell separation chamber 22A positioned upstream of the lysis chamber 22B. Wilding thus fails to teach or suggest the structure recited by Applicants in claim 21. Murphy does not even teach a lysing chamber through which a sample may flow

before being directed to a waste chamber. Thus the references taken alone or in combination, fail to teach the device recited by Applicants in claim 21.

Applicants' device as recited in claim 21 provides important advantages in concentrating cells to be lysed in the lysing chamber, which greatly increases the sensitivity of a test and detection of nucleic acids present in only a low concentration in the sample.

The secondary references do not cure the deficiencies of Wilding and Murphy.

For at least the foregoing reasons, claim 21, and claims 22-35, 37 and 40 depending therefrom, are patentable.

**VIII. CONCLUSION:**

In view of the foregoing arguments distinguishing claims 21-35, 37 and 40 over the art of record, Applicants respectfully submit that the claims are in condition for allowance, and respectfully request that the rejection of these claims be reversed.

Respectfully submitted,



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Encl.: Appendix of claims involved in appeal  
Related Proceeding Appendix (none)  
Evidence Appendix (none)

Claims APPENDIX

LISTING OF CLAIMS:

1.-20. (canceled)

21. (previously presented) A device for extracting an analyte from a sample, the sample containing cells or viruses, the device comprising:
- a) a cartridge having:
    - i) a lysing chamber for lysing the cells or viruses to release the analyte therefrom, wherein the lysing chamber contains capture material for capturing the cells or viruses in the sample as the sample flows through the lysing chamber, the capture material comprises at least one filter or beads, and the lysing chamber is defined by at least one wall having an external surface;
    - ii) at least one waste chamber for receiving used sample fluid that has flowed through the lysing chamber;
    - iii) at least a third chamber for receiving the analyte released from the cells or viruses; and
    - iv) at least one flow controller for directing the used sample fluid, from which the cells or viruses have been separated, to flow into the waste chamber after the sample fluid flows through the lysing chamber and for directing the analyte released from the cells or viruses to flow into the third chamber; and
  - b) a transducer arranged to sonicate the lysing chamber, the transducer being coupled to the external surface of the wall.
22. (previously presented) The device of claim 21, wherein the third chamber comprises a mixing chamber for mixing the analyte with one or more reagents.

23. (previously presented) The device of claim 22, wherein the cartridge further includes a reaction chamber in fluid communication with the mixing chamber for holding the analyte for chemical reaction or optical detection.
24. (previously presented) The device of claim 22, wherein the cartridge further includes:
  - i) a reaction chamber in fluid communication with the mixing chamber for amplifying the analyte; and
  - ii) a capillary electrophoresis area in communication with the reaction chamber.
25. (previously presented) The device of claim 21, wherein the third chamber comprises a reaction chamber for amplifying the analyte and holding the analyte for optical detection, and wherein the cartridge is in combination with an instrument having a heater for heating the reaction chamber and having at least one optical detector for detecting the analyte.
26. (previously presented) The device of claim 21, wherein the third chamber comprises a reaction chamber for amplifying the analyte.
27. (previously presented) The device of claim 21, wherein the wall is dome-shaped and convex with respect to the transducer.
28. (previously presented) The device of claim 21, wherein the wall comprises a sheet or film of polymeric material.
29. (previously presented) The device of claim 28, wherein the wall has a thickness in the range 0.025 to 0.1 mm.
30. (previously presented) The device of claim 21, wherein the wall has stiffening ribs extending radially from a central portion of the wall.

31. (previously presented) The device of claim 21, wherein the cartridge includes a sample chamber having a port for introducing a sample into the cartridge and further includes a sample flow path extending from the sample chamber, the lysing chamber being in the sample flow path.
32. (previously presented) The device of claim 21, wherein the at least one flow controller comprises at least one valve for directing the used sample fluid to flow into the waste chamber via a first flow path in the cartridge and for directing the analyte to flow into the third chamber via a second flow path in the cartridge.
33. (previously presented) The device of claim 21, wherein the capture material comprises at least one filter having a pore size sufficient to capture the cells or viruses.
34. (previously presented) The device of claim 33, further comprising beads in the lysing chamber for rupturing the cells or viruses.
35. (previously presented) The device of claim 21, wherein the capture material comprises beads.
36. (canceled).
37. (previously presented) The device of claim 21, wherein the wall is sufficiently deflectable to deflect in response to vibratory movements of the transducer to generate pressure waves or pressure pulses in the lysing chamber.
38. (canceled).
39. (canceled).

40. (previously presented) The device of claim 21, wherein the capture material comprises a first set of beads for binding the cells or viruses, and wherein the lysing chamber further contains a second set of beads for rupturing the cells or viruses.

41.-75. (canceled)



Related Proceedings Appendix  
none

Evidence Appendix  
none

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Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

## For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)**500.00**

**Complete if Known**

Application Number	09/970,434
Filing Date	October 21, 2003
First Named Inventor	Petersen, Kurt E.
Examiner Name	Nelson C. Yang
Art Unit	1641
Attorney Docket No.	020048-003160US

**METHOD OF PAYMENT (check all that apply)**

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_  
☒ Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee  
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES Small Entity		SEARCH FEES Small Entity		EXAMINATION FEES Small Entity		Fees Paid (\$)
	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Small Entity Fee (\$)	Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

**Total Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**      **Multiple Dependent Claims**  
\_\_\_\_\_ -20 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_      **Fee (\$)**      **Fee Paid (\$)**  
HP = highest number of total claims paid for, if greater than 20  
**Indep. Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**  
\_\_\_\_\_ -3 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_  
HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

**Total Sheets**      **Extra Sheets**      **Number of each additional 50 or fraction thereof**      **Fee (\$)**      **Fee Paid (\$)**  
\_\_\_\_\_ - 100 = \_\_\_\_\_ / 50 = \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: FILING A BRIEF IN SUPPORT OF AN APPEAL

**Fees Paid (\$)****500.00****SUBMITTED BY**

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